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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,924	TENHUISEN ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *See Office Action*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication of February 28, 2005. Applicant's preliminary amendment filed June 24, 2003 is acknowledged and has been entered.

Claims 32-40 are pending and are examined on the merits.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Art Unit 1648.

Information Disclosure Statement

The Information Disclosure Statements received June 24, 2003, and February 28, 2005 have been considered. These documents have been initialed, signed and attached to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "wherein only portion of the antigen is available at a time the immune modulation device is implanted". It is unclear if by reciting "portion of the antigen" the

Applicant refers to the amount of the antigen or the fragment of the antigen. One of the ordinary skill in the art would not be able to practice the currently claimed invention without further clarification or definition of the "portion of the antigen".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed in claims 32-40 without an undue amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the broad concept of "modulating the immune system" encompassed by the claims. Applicant discloses that the modulation of immune system can be both a positive modulation, such as induction of immune responses to antigens derived from various pathogens and a negative modulation such as suppression of the immune response to treat conditions such as allergies and autoimmune diseases (Specification page 19 and 20).

The specification, however, fails to provide sufficient guidance regarding the specific embodiments of the invention, such as the examples of antigens or compounds to be used for the

negative modulation of the immune system. Applicant does not provide any examples of how would the immune system be suppressed using the immune modulation device.

While there are a number of existing approaches to suppression of the immune system, the results of those approaches have not always been promising as reviewed by Wolfraim (Treating autoimmune diseases through restoration of antigen-specific immune tolerance. Arch. Immunol. Her. Exp. Vol. 54, p.1-13). It is well established in the art that the modulation of the immune responses is complex, unpredictable, and well outside the realm of routine experimentation. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claims 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite "wherein only portion of the antigen is available at a time the immune modulation device is implanted". The meets and bounds of term "portion" have not been described in the specification. It is unknown what amount of the antigen is available at the time the immune modulation device is implanted. The skilled artisan would not be able to practice the

current invention without further guidance as to what is the actual amount of the antigen that is going to be available at the time the immune modulation device is implanted. The Applicant did not demonstrate possession of the large genus encompassed by "portion of the antigen". The specification does not provide a structure/function correlation for the antigen portion and the antigens ability to modulate the immune response. There is a lack of a representative number of species of "portion of antigen" that would reasonably represent all antigens or all antigens portions. Thus the Applicant does not have the possession of the claimed genus.

[Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision what would be the amount of the antigen that should be available at the time the immune modulation device is implanted for the antigen to sufficiently modulate the immune system. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al., WO 99/44583 (of record in the June 2003 IDS), in view of the teachings of Sternick et al. (WO 85/03635- of record in the June 2003 IDS).

The claims are drawn to a method of modulating the immune system in an animal to an antigen by implanting within the body of an animal an immune modulation device comprising an impermeable biocompatible shell. The immune modulation device has plurality of pores to allow the ingress and egress of immune cells, an interior lumen, and fibrous scaffolding.

Cerami et al. teach a method of modulating the immune system in an animal to an antigen by implanting within the body of an animal an immune modulation device comprising a porous matrix contained within a perforated but impermeable container (see claim 1). The method and the immune modulation device taught by Cerami are the same as the instantly claimed method and the device, except that the scaffolding inside the shell comprises not a fibrous material, but a porous matrix. Thus, the reference teaches all the limitations of the claimed methods except the use of a fibrous scaffolding within the device.

Sternick et al. teach a method for the induction of an immune response in an animal by implanting a biocompatible substrate with an antigen (see pages 4-5). Sternick et al. teach materials that are useful as the substrate in such methods, such as various types of fibers and meshes (see page 4, lines 17-25). Because the fibrous substrate of Sternick et al. acts in a similar manner to the porous matrix taught by Cerami et al. (i.e. as a support for antigens in a device for the stimulation of the immune response), it would have been obvious to those in the art that fibrous scaffolding is functionally equivalent to the porous matrix of Cerami. Because those in

the art would have recognized that the matrices are functionally equivalent, it would have been obvious to those in the art to substitute the fibrous matrix of Sternick for porous, spongy matrix of Cerami.

One would have had a reasonable expectation of success that the use of a porous, spongy matrix would have worked in Sternick's method because the fibrous substrate of Sternick et al. acts in a similar manner to the porous matrix taught by Cerami et al. The combined teachings of the references therefore render the claimed methods obvious.

Claims 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al., WO 99/44583 (of record in the June 2003 IDS), in view of the teachings of Li et al. (U.S. Patent 6,303,136).

The claims and the teachings of Cerami have been described above. As was indicated above, Cerami et al. teach a method similar to that of the claimed method, except that the device used in Cerami comprises a spongy, rather than a fibrous, matrix within the device.

The Li reference teaches an implantable device for the containment of cells. While this device is not described as useful for modulating an immune response, it is intended for the encapsulation of cells in a host environment (see column 1).

The structure of the device described by Li (col. 1, lines 17-26) is similar to that of the Cerami device. The devices differ in that, in the Li device, the outer membrane is impermeable to large molecules and cells, whereas Cerami's device is made permeable to immune cells through perforation of the outer shell. Additionally, Li teaches that the cells within the device are preferably placed on a fibrous scaffolding, such as yarn or mesh scaffolding (see column 2, lines

29-43), whereas Cerami teaches a porous matrix, and indicates that such matrix may be a sponge-like material (see page 9, lines 1-6). Because Li teaches a device for the encapsulation of cells, and Cerami teaches a method of modulating the immune system by implanting within the body of an animal an immune modulation device, it would have been apparent to those in the art that the matrices taught by Li and Cerami were functionally equivalent as providing support for cells in an implanted device. It would therefore have been obvious to those in the art to use a fibrous matrix taught by Li in the device taught by Cerami.

Those in the art would have had a reasonable expectation of success in the combination because other teachings in the art indicate that the multiple materials may be used in to form matrices for implantable immune devices. See e.g., WO 85/03635, pages 4-5 (of record in the June 2003 IDS). Thus, the combined teachings of Cerami and Li render the claimed methods obvious.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

June 7, 2006

Stacy B. Chen 6/7/06

Stacy B. Chen
Primary Examiner